

EXHIBIT J

PARRISH LAW OFFICES

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March 19, 2019

VIA PRIORITY MAIL

DHHS – OMHA
Centralized Docketing
Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

BENEFICIARY APPEAL

RE: Request for ALJ Hearing

Beneficiary: Anniken Prosser

W2973 Farmstead Drive

Appleton, WI 54915

HICN: 4R87U71QM75

Device: Tumor Treatment Field Therapy (E0766)

Supplier: Novocure, Inc.

Dates of Service: 5/16/18, 6/16/18, 7/16/18

Medicare Appeal No: 1-8251666390

Date of QIC Decision: March 15, 2019

Our Ref: 19-52

Dear Claims Coordinator:

As an authorized representative of the above-captioned Medicare beneficiary, Anniken Prosser, I hereby appeal to an Administrative Law Judge the above-captioned decision rendered by the Qualified Independent Contractor (“QIC”) C2C Innovative Solutions, Inc. for the claim submitted for tumor treatment field therapy (“TTFT”) for a glioblastoma. The QIC denied the claim stating “the medical documentation of the efficacy of this device is not within the usual scope and breadth of current medical literature with peer acknowledgement and review.” The QIC found the “clinical trials to be limited in number and asserted the clinical trials were biased because they were funded by Novocure. The QIC also asserts that although the DMACs acknowledged a valid reconsideration request was filed, LCD L34823 remains applicable until the DMACs retire it or issue a new LCD.

The published, peer-reviewed literature shows the improved clinical survival and the progression-free survival of patients who receive TTFT for their glioblastoma. TTFT for glioblastoma is included in the National Comprehensive Cancer Network (“NCCN”) guidelines and is considered the standard of care for newly diagnosed glioblastoma. Hundreds of treating


physicians, in all 50 states, have prescribed TTFT. TTFT is covered by all the large national payers. Medicare has paid for numerous claims for medically indistinguishable beneficiaries.

The QIC's determination is nonsensical. The seminal articles showing the effectiveness of the treatment/device were published in JAMA, one of the most prestigious journals in the country based on "impact factor." JAMA is a peer-reviewed publication, thus the assertion that the documentation lacks review is belied by the evidence. Multiple peer-reviewed articles show the effectiveness of the device to there is scope and breadth. The inclusion of TTFT in the NCCN guidelines is "peer acknowledgment and review."

Finally, it is customary in the United States for clinical trials to be sponsored. Indeed, Medicare often requires industry to sponsor a study as a condition of Medicare coverage. Industry sponsored clinical trials underpin most Medicare LCDs. In the present case, the authors of the papers are at academic institutions and the paper went through peer-review thus eliminating or managing any bias that may have derived from the studies' sponsorship. A standard that precludes consideration of industry-sponsored research for purposes of Medicare coverage would preclude consideration of most of the biomedical research, a clearly absurd result.

In either event, on March 6, 2019, the Medicare Carrier Advisory Committee voted to extend Medicare coverage of TTFT based on the studies completed in 2017. Thus, no basis exists for denying coverage.

Yours very truly,



Debra Parrish on behalf of
Ms. Anniken Prosser

Enclosures:

Attachment A: Appointment of Representative Form
Attachment B: Certificate of Service

cc: Ms. Anniken Prosser
Novocure, Inc.

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April 10, 2019

VIA PRIORITY MAIL

Judge Lissette Figueroa
Office of Medicare Hearings and Appeals
Miami Field Office
51 SW 1st Ave., Suite 1536
Miami, FL 33130

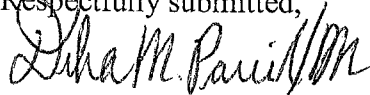
RE: Prehearing Brief
ALJ Appeal No. 1-8380637906
Appellant/Beneficiary: A. Prosser
Service: E0766
Dates of Services: 5/16/18, 6/16/18, 7/16/18
Hearing Date: TBD
Our Ref. No.: 19-52

Dear Judge Figueroa:

In anticipation of the scheduling of the above-captioned case, please find attached a prehearing brief to aid in your analysis. We have compiled (1) additional studies from 2018 and 2019 and (2) textbook chapters from medical textbooks since the filing of the reconsideration request, which are included on the attached CD. The LCD Record Exhibit List detailing the documents considered by the contractor for L34823 is also included.

If you have any questions regarding the foregoing, please do not hesitate to contact me at (412) 561-6250. We appreciate your consideration.

Respectfully submitted,



Debra M. Parrish
Attorney for A. Prosser

Enclosures:

Attachment A: Prehearing Brief
Attachment B: CD containing:
-LCD Record Exhibit List
-TTFT bibliography for GBM & additional peer-reviewed studies from 2018 & 2019 -
(aside from those previously submitted with the reconsideration request)
-Medical school textbook excerpts

cc: Ms. A. Prosser